

**AMENDMENT**

U.S. Appln. No. 10/768,094

**REMARKS**

Initially, Applicants note that the Examiner has not acknowledged Applicants' claim to foreign priority, and has not indicated whether the certified copy of the priority document has been received.

Accordingly, the Examiner is requested to acknowledge Applicants' foreign priority claim and indicate that the priority document has been received.

The claims have been amended to clarify the claim language, e.g., to make the language more concise, for example by using the abbreviations set forth in the specification, and to grammatically emphasize the order of the procedures.

Claim 1 has also been amended to incorporate Claim 2 therein, and Claim 2 has been cancelled.

On page 2 of the Office Action, Claims 1-14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Specifically, the Examiner contends that the term "identical in HLA type" renders the claims indefinite. The Examiner notes that U.S. Patent 6,558,662 to Sykes et al. appears to define the term as meaning a 6 of 6 match in HLA antigens. The Examiner nevertheless indicates that, for purposes of examination, she will read the term to encompass some mismatches.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully submit that the Examiner's interpretation of the term "identical" as encompassing some mismatches in HLA antigens is contrary to the definition shown

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in Sykes et al (which is the ordinary meaning of the term "identical in HLA type" in the art), and is contrary to the plain meaning of the word "identical." "Identical in HLA type" clearly means to one skilled in the art that all 6 HLA types (i.e., two sets of A, B and DR) are identical.

Accordingly, Applicants respectfully submit that the claims clearly and definitely recite the invention of interest, and thus request withdrawal of the Examiner's rejection.

On pages 3-5 of the Office Action, Claims 1-7, 10 and 12-14 are rejected under 35 U.S.C. §102(e) as being anticipated by Sykes et al (U.S. Patent 6,558,662).

Specifically, with respect to the independent claims, the Examiner contends that Sykes et al discloses a method for treating a malignant tumor comprising: thymic irradiation, bone marrow transplantation, donor lymphocyte transfusions at days 35 and 56, and thymic irradiation (column 20, lines 57-67).

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Claim 1 of the present application comprises the following steps 1 to 4 below:

1. Donor lymphocyte infusion (DLI),
2. Radiation treatment (irradiation),
3. Infusion of lymphocytes derived from the host or a third party identical in HLA type to the host, and
4. Intra bone marrow-bone marrow transplantation using bone marrow cells derived from the host (IBM-BMT).

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Claim 10 of the present application comprises the following steps 1, 2 and 5:

1. Donor lymphocyte infusion (DLI),
2. Radiation treatment (irradiation), and
5. Intravenous administration of peripheral blood stem cells derived from the host or a third party identical in HLA type to the host (PBSC).

Claim 13 of the present application comprises:

2. Radiation treatment (irradiation),
3. Infusion of lymphocytes derived from the host or a third party identical in HLA type to the host, and
4. Intra bone marrow-bone marrow transplantation using bone marrow cells derived from the host (IBM-BMT).

More specifically, Claims 1, 10 and 13 of the present invention comprise steps 3-4 or 5 which involve using "host cells" (i.e., cells derived from the host or a third party identical in HLA type to the host).

By the introduction of said host cells, the actions and effects described in page 9, line 6 et seq., of the specification of the present application are achieved.

On the other hand, Sykes et al discloses a method comprising the following steps A to E (see column 20, lines 57 to 67):

- A. Conditioning therapy (with thymic irradiation, etc.) and BMT,

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- B. GVHD prophylaxis (with anti-thymocyte globulin, etc.),
- C. Post-transplant supportive care (with antibiotics, etc.),
- D. Donor leukocyte infusions, and
- E. Thymic irradiation.

Sykes et al does not teach or suggest the use of "host cells", as recited in Claims 1, 10 and 13 of the present application.

Accordingly, Applicants respectfully submit that the present invention is not taught in Sykes et al, and thus request withdrawal of the Examiner's rejection.

On page 6 of the Office Action, Claims 1-13 are rejected under 35 U.S.C. §103(a) as being obvious over Sykes et al (U.S. Patent 6,558,662) in view of Askenasy (*Stem Cells*, 20:86-93 (2002)).

Specifically, with respect to Claims 8 and 9, the Examiner contends that Askenasy teaches that isolated limb perfusion and intra-bone marrow transplantation improves the efficiency of the bone marrow graft in non-myeloablated patients (page 87, first column, first full paragraph).

The Examiner contends that it would have been obvious to carry out bone marrow transplantation into the bone of the patient having undergone low-level thymic irradiation.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Sykes et al does not teach or suggest the concept of replacing the donor-derived hematopoietic system with the

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hematopoietic system of the host (reconstruction of the latter system), or suggest any actions or effects attained by the introduction of "host cells", as claimed and achieved in the present invention.

Moreover, Askenasy clearly does not provide the deficiencies which exist in Sykes et al.

Accordingly, Applicants respectfully submit that the present invention is not taught in Sykes et al, alone or when combined with the teaching of Askenasy, and thus request withdrawal of the Examiner's rejection.

In view of the amendments to the claims and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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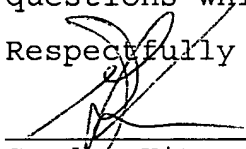
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